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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,725	10/19/2004	Toshiro Omori	042872	2520

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EXAMINER

CLARK, AMY LYNN

ART UNIT PAPER NUMBER

1655

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/511,725

Applicant(s)

OMORI ET AL.

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/19/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-7, drawn to a composition having an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it, the composition comprising of an unadsorbed fraction which is formed by subjecting a barley *shochu* stillage byproduced in the production of *shochu* from a barley as a raw material to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment to adsorption using a synthetic adsorbant, in which the unadsorbed fraction contains plural peptides.

Group II, claims 8-10, drawn to a process for producing a composition having an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it and comprising an unadsorbed fraction, which comprises a step of subjecting a barley *shochu* stillage byproduced in the production of *shochu* from barley as a raw material to solid-liquid separation to obtain a liquid fraction and a step of subsection the liquid fraction to a separation treatment by adsorption using a synthetic adsorbed fraction, in which the unadsorbed fraction contains plural peptides.

Group III, claims 11-13, drawn to a process for producing a barley *shochu* and a composition comprising an unadsorbed fraction, characterized by comprising a step of fermenting a barley koji produced from a husked barley or a polished barley as a raw material and a *shochu* yeast to form a mature mash and distilling the mature mash to produce the barley *shochu* and a step of subjecting a barley *shochu* stillage byproduced in the production of the barley *shochu* to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbant to obtain the unadsorbed fraction, in which the unadsorbed fraction contains plural peptides.

Group IV, claims 14-20, drawn to a food composition having an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it, the composition comprising of an unadsorbed fraction which is formed by subjecting a barley *shochu* stillage byproduced in the production of *shochu* from a barley as a raw material to solid-liquid

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separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment to adsorption using a synthetic adsorbant, in which the unadsorbed fraction contains plural peptides.

Group V, claims 21-23, drawn to a process for producing a food composition having an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it and comprising an unadsorbed fraction, which comprises a step of subjecting a barley *shochu* stillage byproduced in the production of *shochu* from barley as a raw material to solid-liquid separation to obtain a liquid fraction and a step of subsection the liquid fraction to a separation treatment by adsorption using a synthetic adsorbed fraction, in which the unadsorbed fraction contains plural peptides.

Group VI, claims 24-26, drawn to a process for continuously producing a barley *shochu* and food composition comprising an unadsorbed fraction, characterized by comprising a step of fermenting a barley koji produced from a husked barley or a polished barley as a raw material and a *shochu* yeast to form a mature mash and distilling the mature mash to produce the barley *shochu* and a step of subjecting a barley *shochu* stillage byproduced in the production of the barley *shochu* to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbant to obtain the unadsorbed fraction, in which the unadsorbed fraction contains plural peptides.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is drawn to a composition having an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it, the composition comprising of an unadsorbed fraction which is formed by subjecting a barley *shochu* stillage byproduced in the production of *shochu* from a barley as a raw material to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment to adsorption using a synthetic adsorbant, in which the unadsorbed fraction contains plural peptides. The special technical feature of Group II is drawn to a process for producing a composition having an activity of

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inhibiting the onset of alcoholic hepatopathy and an activity of healing it and comprising an unadsorbed fraction, which comprises a step of subjecting a barley *shochu* stillage byproduced in the production of *shochu* from barley as a raw material to solid-liquid separation to obtain a liquid fraction and a step of subsection the liquid fraction to a separation treatment by adsorption using a synthetic adsorbed fraction, in which the unadsorbed fraction contains plural peptides. The special technical feature of Group III is drawn to a process for producing a barley *shochu* and a composition comprising an unadsorbed fraction, characterized by comprising a step of fermenting a barley koji produced from a husked barley or a polished barley as a raw material and a *shochu* yeast to form a mature mash and distilling the mature mash to produce the barley *shochu* and a step of subjecting a barley *shochu* stillage byproduced in the production of the barley *shochu* to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbant to obtain the unadsorbed fraction, in which the unadsorbed fraction contains plural peptides. The special technical feature of Group IV is drawn to a food composition having an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it, the composition comprising of an unadsorbed fraction which is formed by subjecting a barley *shochu* stillage byproduced in the production of *shochu* from a barley as a raw material to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment to adsorption using a synthetic adsorbant, in which the unadsorbed fraction contains plural peptides. The special technical feature of Group V is drawn to a process for producing a food composition

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having an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it and comprising an unadsorbed fraction, which comprises a step of subjecting a barley *shochu* stillage byproduced in the production of *shochu* from barley as a raw material to solid-liquid separation to obtain a liquid fraction and a step of subjection the liquid fraction to a separation treatment by adsorption using a synthetic adsorbed fraction, in which the unadsorbed fraction contains plural peptides. The special technical feature of Group VI is drawn to a process for continuously producing a barley *shochu* and food composition comprising an unadsorbed fraction, characterized by comprising a step of fermenting a barley koji produced from a husked barley or a polished barley as a raw material and a *shochu* yeast to form a mature mash and distilling the mature mash to produce the barley *shochu* and a step of subjecting a barley *shochu* stillage byproduced in the production of the barley *shochu* to solid-liquid separation to obtain a liquid fraction and subjecting the liquid fraction to a separation treatment by adsorption using a synthetic adsorbant to obtain the unadsorbed fraction, in which the unadsorbed fraction contains plural peptides. Finally, Claim 11, at least, is anticipated by or obvious over Sakurai et al. (JP06-098750, 12.04.1994). Sakurai teaches a method for producing barley *shochu* and a concentrated product from the residue of the *shochu* comprising the steps of fermenting the barley, distilling the liquor off to give the barley *shochu* and filtering the *shochu* with a filter press, through a filter cloth, which reads on adsorbant material. Sakurai does not expressly teach an unadsorbed fraction of barley *shochu* comprising of plural peptides with an average chain length of 3 to 5, wherein the peptides comprise from 24 to 38% glutamic acid,

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from 4 to 20% glycine, from 5 to 10% aspartic acid, from 4 to 9% proline, from 5 to 10% aspartic acid and from 4 to 8% serine in terms of an amino acid composition ratio when the total content of amino acids derived from the peptides is defined as 100%, an activity of inhibiting the onset of alcoholic hepatopathy and an activity of healing it are provided, however, the process as taught by Sakurai is one and the same as the process claimed by Applicant and the peptides comprising of the amino acids listed are inherent to the concentrated product also taught by Sakurai. Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so the invention lacks unity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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AU 1655

Amy L. Clark
April 3, 2006

Michele P. Flood
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PRIMARY EXAMINER